HFE-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL –3846-0
July 26, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert H. Hamor, M.D.
Chairman of Radiology
Department of Radiology
Summa Health System-Akron City Hospital
525 East Market St.
Akron, OH 44309

Facility I.D.#: 150474

Dear Dr. Hamor:

We are writing to you because on July 18, 2000, your facility was inspected by a representative of the State of Ohio, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

> Your records revealed that your facility phantom quality control records for the mammography unit were missing for four weeks. The MQSA regulation requires the mammography unit be evaluated by performing at least weekly the image quality evaluation test. The inspection found that your facility failed to perform this quality control test during the weeks of December 27, 1999, January 3, 10 and 17, 2000. **21 CFR 900.12(e)(2)**

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, this condition represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 noncompliance item that was listed on the inspection report provided to you at the close of the inspection. This Level 2 noncompliance item is:

> Your records showed that no corrective actions were documented for the weeks of August 30, 1999, February 11, May 8 and May 18, 2000 for phantom images that failed to meet the required score, and mammograms were performed on these dates without performing an additional phantom image quality control test. **[21 CFR 900.12(e)(2)(iii)), as required by 21 CFR 900.12(e)(8)(ii)].**
>
> **Please note this noncompliance item was also observed by the inspector during the July 21, 1998 MQSA inspection. The 1998 noncompliance item was listed as a Level 3 noncompliance item in the post inspection report. This report was provided to your facility at the close of the inspection in 1998.**

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the violations noted in this letter; and
- each step your facility is taking to prevent the recurrence of similar violations.

Please include sample records with an explanation that demonstrates proper record keeping procedures that are now being followed. (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

> Mr. R. Terry Bolen
> MQSA Compliance Officer
> Food and Drug Administration
> 6751 Steger Dr.
> Cincinnati, OH 45237-3097

Also, please send a copy to the State radiation control office:

> Ms. Terri Eckert
> Ohio Department of Health
> 161 South High St, Suite 400
> Akron, OH 44308

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address all other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Mr. R. Terry Bolen at (513) 679-2700, extension 138.

Sincerely yours,

Carol A. Heppe

Carol A. Heppe
Acting District Director
Cincinnati District Office

c.
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